No. 21113

United States Court of Appeals

For the Ninth Circuit

DAVID R. GOLDEN, *Appellee*,

vs.

RICHARDSON-MERRELL, INC., a corporation, *Appellant*.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON, NORTHERN DIVISION

BRIEF OF APPELLANT

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United States Court of Appeals
For the Fifth Circuit

DAVID R. GOLDEN,	*Appellee*,	
vs.		No. 21113
RICHARDSON-MERRELL, INC., a corporation,	*Appellant*.	

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON, NORTHERN DIVISION

BRIEF OF APPELLANT

FACTS OF JURISDICTION AND RESUME OF PLEADINGS

Plaintiff-appellee, David R. Golden, a Washington State resident, brought suit for $250,000.00 against defendant-appellant, Richardson-Merrell, Inc., a Delaware corporation[1] and manufacturer of drugs, under authority of 28 USC 1332. This court is vested with appellate jurisdiction (R. 13, Tr. 1539) under 28 USC 1291.

Appellee's Amended Complaint (R. 13) as modified by pre-trial order (R. 78) generally alleged that, as a result of taking a physician-prescribed cholesterol inhibiting drug, known as MER/29, which was manufactured by appellant,[2] appellee suffered ". . . eye disease and cataracts, damage to his scalp and hair, damage to

[1] Although jurisdictional facts were not pleaded originally (R. 1 and R. 13), diversity of citizenship is stated to exist in par. 1 of pre-trial order (R. 78).

[2] Actual production of MER/29 was by a subsidiary, Wm. S. Merrell Co., Cincinnati, Ohio.

his skin . . .'' etc.; that appellant was liable to appellee on the theory of (1) negligence (first cause of action) (2) express and implied warranties (second cause) and (3) fraud (third cause of action) (R. 13).

Appellant denied liability under all of these theories (R. 23).

STATEMENT OF THE CASE

A. Underlying Disease

Atherosclerosis (hardening of the arteries) is characterized by the formation of ''plaques'' in the arteries, and according to Dr. Miller, appellee's attending physician,[3] it was felt by him ''and by doctors generally that there is a relation of cholesterol to the formation of atherosclerotic plaques'' (Tr. 55). ''As is generally known, there is a great concern in this country in regard to heart disease . . . and there is a great deal of experimental work going on in this field, that there is a feeling . . . that cholesterol and fat have something to do with . . . heart attacks'' (Tr. 56). Indeed, ''it (atherosclerosis) is one of the most, if not the most, important single diseases in humans in this country''[4] (Tr. 1393).

B. Brief History of MER/29

Responding to this concern, appellant's research chemists, having undertaken the challenge in 1952, produced hundreds of related compounds by ''molecular manipulation'' over the next several years until finally

[3] He had attended appellee since April of 1955 (Tr. 36, l. 3).

[4] This description by Dr. J. Earle Estes, 12 years on staff of Mayo Clinic and past-president of American College of Angiology (Tr. 1391).

MER/29 was synthesized in 1956 (Tr. 1104-1107). It was first subjected to extensive laboratory animal testing, and in 1958 and 1959 selected clinical investigators, such as Dr. J. Earle Estes of the Mayo Clinic, treated consenting cardiovascular patients with the new drug on an experimental basis[5] (Tr. 1396-1404). A new drug application was filed with the Food and Drug Administration in July, 1959 under the then[6] provisions of 21 USC 355, and the drug was approved for prescription sale in April of 1960 (Tr. 1646, ll. 12-14).

C. Labeling of MER/29

The labeling of MER/29, approved by the FDA for dissemination to physicians, and to be included in the packages sent to pharmacists, stated, *inter alia*:

> "MER/29 is well tolerated at a dose of 250 mg. daily. Infrequent side effects have occurred but their incidence is too low for positive correlation with administration of the drug. Isolated reports have been received of nausea, vomiting, temporary vaginal bleeding, and dermatitis.
>
> "Hypercholesterolemia and its associated conditions may require MER/29 therapy over a long period. MER/29 has been shown to be entirely safe in the periods the drug has been studied, but long-term or lifetime effects are unknown. Periodic examination of patients on long-term MER/29 therapy is therefore necessary.
>
> "While clinical liver damage has not been encountered, periodic liver function tests may be desirable until more long-term safety data are available." (Ex. A-1, Tr. 1229)

[5] These clinical investigators conferred on their experiences at Princeton, N.J., December, 1959 (Tr. 1403).

[6] 21 USC 355 was amended by Sec. 101-104 of Public Law No. 87-781 October 10, 1962, 76 Stat. 780. For text of 21 USC Sec. 355 at that time in effect, see Appendix A herein.

D. Eventual Withdrawal from Market

After appellant's medical research department had investigated reports of hair loss by some patients, it proposed to the FDA and was permitted to include a "thinning of the hair" warning. Later, on December 1, 1961, having verified the possible relationship of lenticular opacities in certain patients to ingestion of the new drug, appellant proposed to the FDA and was permitted to send a warning letter to all physicians (Ex. A-5, Tr. 1191).[7] Additional reports of cataracts in early 1962 resulted in recommendation by appellant's medical staff that the drug be withdrawn from the market and, accordingly, appellant discontinued sales in April, 1962. Formal suspension of the "effectiveness of . . . (the new drug) application" was ordered by the Secretary of Health, Education and Welfare on May 22, 1962, under 21 USC 355 (e) (1)[8] (Tr. 1646).

During its period of marketing, some 442,000 patients had taken MER/29 (Tr. 1149-50). All side effects combined affected substantially less than 1% of those treated (Tr. 1224). The drug was admittedly effective in reducing cholesterol[9] (Tr. 154, ll. 18-20).

---

[7] The jury was entitled to find this letter was not received by appellee's physician (Tr. 176, ll. 14-15).

[8] 355 e (1) covers suspension based on a finding "that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under conditions of use upon the basis of which the application became effective, . . ." 21 USC Sec. 355 (e) (1).

[9] This opinion of appellee's doctor was shared by all the medical witnesses who were asked, although reluctantly by appellee's witness, Dr. Loomis (Tr. 516, ll. 18-21).

E. Plaintiff-Appellee's Reaction

Appellee, David R. Golden, patient of Doctor Milton J. Miller (both of Seattle, Washington), was one of those few who apparently suffered side effects. He was placed on MER/29 therapy on September 27, 1960. Following his prescribing the drug, Dr. Miller saw his patient on December 1, 1960, and once again on September 11, 1961, until, by telephone, he ordered discontinuance on March 28, 1962 (Tr. 93, ll. 14-16).

> "Mr. Golden called on March 28, 1962, and stated that his skin was becoming dry and he was advised to stop MER/29." (Tr. 93)

Thereafter, a "folliculitis"[10] of his skin allegedly was changing from a blonde color to gray" (Tr. 98). He was hospitalized twice for the folliculitis (Tr. 100-103, 111-112). On February 18, 1963, he told Dr. Edward Schwartz, an opthomologist to whom he had been referred, that his vision had been getting progressively "blurry" for four or five months. Early cataracts were then diagnosed (Tr. 118-119). Later, on May 18, 1963, he was seen by another opthomologist, Dr. Leland Watts (Tr. 122, 531), who surgically removed the cataracts from the left eye June 26, 1963, and from the right eye August 14, 1963. He was fitted with contact lenses which restored visual acuity to 20-20 (Tr. 554) but the surgery left him deficient in accommodation to range, protection against light, sensitivity, peripheral vision,

[10]"Inflammation of a group of follicles." New Gould Medical Dictionary First Edition 1951.

physical appearance of the pupil (Tr. 555, 560, 561), developed (Tr. 96), and "his hair was receding and . . . and left him more subject to later glaucoma and retinal detachment than the average person (Tr. 565).

Dr. Watts was clear in his opinion that appellee's cataracts were related to MER/29 ingestion (Tr. 542) although he conceded that he did not necessarily mean that the drug itself was toxic (Tr. 569-570). This doctor admitted that appellee's were the only cataracts, so related, that he had ever seen (Tr. 549). He removed "25 to 30 cataracts a year" (Tr. 567).

F. The Trial

Trial of this action commenced March 21, 1966, and ended April 6, 1966. A considerable portion of the testimony was by way of depositions taken in New York both by appellant and by representatives for a national plaintiff's "group"[11] of which appellee's counsel is a member.

A considerable portion of the evidence consisted of reports of data submitted to the FDA as part of the appellant's new drug application[12] and testimony in respect thereto.

At the outset of the trial (Tr. 4) appellant requested "ground rules" that would exclude any evidence going to the issue of fraud on the part of appellant based on

[11] (Tr. 780, ll. 12-13; Tr. 781, ll. 9 and 10).

[12] The New Drug application consisted of five volumes of material. It was from this mass that certain omissions and inaccuracies in reporting were alleged to exist (Tr. 213, l. 25).

alleged omissions or inaccuracies in its reporting to the FDA and urged that the Court "ought not to permit the jury to speculate as to what the Food and Drug Administration might have done if they had some tests that were not turned into the Food and Drug Administration" (Tr. 4, ll. 22-25).

Later, motions for a directed verdict on the issues of fraud and both express and implied warranty were made at the close of plaintiff's case in chief and, after both parties had rested, on the ground of insufficiency of the evidence, and that implied warranty properly should not be applied to a prescription drug case. All of these motions were denied (Tr. 993, 1007, 1532).

Instructions were given the jury on all of plaintiff's theories including the theory that the jury might find damages to the plaintiff as a result of either fraudulent reporting of data to the FDA or negligence (Tr. 1659, l. 15-Tr. 1660, l. 21).

The jury returned a verdict for appellee in the amount of $150,000.00 (R. 140) upon which judgment was thereafter entered (R. 141).

Motion for Judgment NOV or for New Trial was made under FRCP Rule 50 (b) 28 USC (R. 145-147) and thereafter denied on April 25, 1966 (R. 150).

This appeal follows (R. 152).

SPECIFICATION OF ERROR No. 1

The District Court erred in submitting that portion

of its charge, reading in *totidem verbis*:

> "The laws of the United States require that before the defendant could sell MER/29 to the public it must file what is called a 'New Drug Application' with the Food and Drug Administration which application shall contain full reports of all investigations which have been made to show whether or not such drug is safe for use and if you find that the defendant failed to make full reports of all investigations it made of the drug MER/29, at the time it filed its New Drug Application or the supplement thereto, then such failure on the defendant's part in violation of the law, would be negligence, *per se,* for which the defendant would be liable to the plaintiff for any damages proximately resulting therefrom and because of the defendant." (Tr. 1659-1660)

At the time of the trial, and before the jury retired to deliberate, appellant noted the following objection:

> "Except to the Court's instruction to the jury that the jury may find damages for the plaintiff consequent upon any negligence of filing inaccurate data on the part of the defendant in the Food and Drug Administration, if they find that such resulted in damage to the plaintiff. Now, the evidence indicates this, and I think it is substantially uncontroverted that the defendant promulgates certain types of condensed reports quite incidental in literature that accompanies its products. The literature included a great deal more and greater emphasis, of course, was placed upon the clinical work in advising physicians of this. Now, the point of this, this permits the jury to speculate as to a possible connection between inaccurate reporting. There is no direct evidence of such connection, and this invitation to speculate is, we submit, erroneous and prejudicially so.
>
> "THE COURT: Allowed." (Tr. 1686)

As a matter of law the evidence is not sufficient to establish that plaintiff was damaged by inaccurate reporting to the FDA, and the jury, by the giving of this instruction, was invited to speculate that the labeling approved by the FDA would have contained results of omitted tests, etc., and that this additional or different material would have caused the plaintiff's doctor to forego prescribing MER/29.

SPECIFICATON OF ERROR No. II

The District Court erred in submitting that portion of its charge reading in *totidem verbis,* as follows:

> "Plaintiff contends that defendant practiced fraud upon the Food and Drug Administration in respect to animal testing.
>
> "I instruct you that the nature of proof to support such a claim of fraud is different from the proof of most other issues. The evidence must be clear, cogent and convincing. In this case, before you can find that fraud existed or occurred as alleged by plaintiff, it is necessary that by clear, cogent and convincing evidence you find that each and all of the following elements of fraud existed or occurred, namely:
>
> (1) A representation of existing fact;
> (2) Its materiality;
> (3) Its falsity;
> (4) The speaker's knowledge of its falsity;
> (5) His intent that it shall be acted upon by the person to whom it is made;
> (6) Ignorance of its falsity on the part of the person to whom the representation is made;
> (7) The latter's reliance on the truth of the representation;
> (8) His right to rely upon it; and
> (9) His consequent damage." (Tr. 1665, line 6 through 1666, line 3)

At the time of trial, and before the jury retired to deliberate, appellant noted the following objection to the above charge:

> "Except also to that instruction which advises the jury that they may find fraud on the plaintiff by virtue of the accused and purportedly proved fraud on the department. It is somewhat in the same vein as the previous one,[13] but with this additional interpretation. Raw data is submitted to the department. It is analyzed and it is scrutinized, examined, and then the department either says this is adequate or this is not adequate, then when the time comes for there to be made printed matter that is part of what is called labeling and in no case that there is *hair* (*sic,* 'here') is there any labeling showing any tendency whatever the slightest tendency to indicate that any fraud, inaccuracy or by whatever name one desires could be in this was intended to be made to any individual outside the Food and Drug Administration and the permission to let them speculate is equally offensive *if* (*sic,* 'in') this as it was in others and it is offensive more for the reason that there is no cause of action on fraud flowing to this plaintiff as was pointed out in our previous contentions as a matter of law. (Interpolations added)
>
> "THE COURT: Allowed." (Tr. 1686-1687)

This charge could only be construed by the jury to mean that the plaintiff might recover if it found that the reported data which formed a part of the New Drug Application contained inaccuracies or misrepresentations or was not complete, even though whatever remote and indirect reliance by plaintiff might be found, the same would necessarily require speculation that, except for these inaccuracies, misrepresentations and omis-

[13]The reference was to the instruction set out in Specification 1.

sions, the marketing of the drug would not have been approved, or that the labeling would have been different.

SPECIFICATION OF ERROR No. III

The Court erred in denying defendant's motion for a directed verdict on the issue of fraud, particularly as to fraud on the FDA made at the close of plaintiff's case. This motion may be found at page 993 of the transcript, lines 2 through 12 and reasons given in support thereof from Tr. 993, line 13 through Tr. 1004, line 4.

SPECIFICATION OF ERROR No. IV

The Court erred in denying defendant's motion for a directed verdict on the issue of fraud, particularly as to fraud on the FDA, made at the close of all of the evidence. This motion and the reasons given therefor appear from page 1532 of the transcript, line 19 through page 1534, line 18.

SPECIFICATION OF ERROR No. V

The Court erred in denying the defendant's motion for a directed verdict on the issue of express warranty made at the close of plaintiff's case. This motion may be found on page 993 of the transcript and the reasons given in support thereof at pages 1004, line 5 through 1007, line 17.

SPECIFICATION OF ERROR No. VI

The Court erred when it denied the renewal of the motion described in Specification No. V at the close of all the evidence. This motion may be found from page

1532, lines 19 through 24 and the argument in support thereof from pages 1535, line 19 through 1537, line 2 of the transcript.

SPECIFICATION OF ERROR No. VII

The Court erred in denying defendant's motion for a directed verdict on the issue of implied warranty at the close of plaintiff's case. This motion may be found at page 993, lines 2 through 12 of the transcript and the argument thereon at page 1007, lines 16 through 25.

SPECIFICATION OF ERROR No. VIII

The Court erred when it denied the renewal of the motion described in Specification No. VII at the close of all the evidence. This motion may be found from page 1532, line 19 through 24 and the argument in support thereof from pages 1535 line 19 through 1537, line 2.

SPECIFICATION OF ERROR No. IX

The Court erred when it admitted in evidence over the strenuous objection of the appellant promotional material of the appellant in the absence of proof that Dr. Miller, the prescribing doctor, relied on it or that Mr. Moberg, the representative of the appellant who called on the doctor, communicated said material to him.

ARGUMENT

Introduction to Argument

A shotgun blast into the twelve volumes of this record would doubtlessly hit a multitude of technical error. Despite how conscientious a trial judge may be, for him to conduct a trial of this length and escape all error would

require that he be unreal. Neither appellate courts nor litigants can expect as much. Certainly, that is why the test of any review is reduced to one of *prejudicial* error. And that is why we have aimed to avoid picayune herein and the prolixity which is its inevitable companion.

We must shamefully confess that, although some of the "shot" might have struck substantial errors, other than herein assigned, we must forego complaint because we were human too, and proper foundation in some instances was overlooked.

Because of the nature of the errors herein specified, we have felt bound to furnish a record of the trial in its entirety.[14] We do not envy the court's task in reviewing this record. At the same time, although ever mindful that review of the errors herein considered will be based upon an acceptance by the court of appellee's *most favorable evidence,* we still feel that a review of the entire record will show the court the *sui generis* complexion of prescription new drug cases—their essential distinction from the usual food, drug or cosmetic case—where, as here, scientists work long and hard to produce a wholesome and unadulterated[15] drug that has an *action* on the human body that the medical profession eagerly *wants*, and then it turns out that the very action desired has apparently adversely affected some patients in

[14] *United States v. John II Estate* (CCA Hawaii 1937) 91 F.2d 93.

[15] It will be noted that the record is devoid of any evidence showing the least impurity.

other organs or bodily systems in a manner doctors did not expect.

Summary of Order of Argument

Specifications I and II both involve a common alleged deficiency in the evidence of causal relationship, between alleged negligent or fraudulent reporting of data to the FDA and the injury claimed, and to avoid repetition will be discussed together (Specifications III and IV relate to the same common issue, except only they concern denial of motions rather than complaint of instructions).

Specifications V and VI relate to mid-trial motions and VII and VIII to "end of trial" motions all involving either "express" or "implied" warranty and will be discussed under appropriate headings.

ARGUMENT ON SPECIFICATIONS I and II

Specifications I and II will be discussed together. The first concerns an erroneous instruction in respect to alleged *negligent* reporting to the FDA, whereas Specification II concerns an erroneous instruction respecting alleged *fraud* on the FDA. Obviously, in a case such as this, the element of reliance by a plaintiff required to be established in a fraud cause, is essentially the same as the required element of proximate cause in a negligence action. And, so far as a *legal* failure of proof of causation is concerned, both, it would seem, may suffer from the same broken link. We might here point out that the trial judge was well apprised of ap-

pellant's insistent contention that there was a legally fatal hiatus in the evidentiary chain of causation, specifically that the record was devoid of evidence that the FDA *would have suspended the new drug application or changed its labeling* if these alleged deficiencies in reporting data had come to its attention (Tr. 1000, l. 13-1004, l. 4 and 1532, l. 19-1535, l. 18). Over strenuous and repeated objections, the witness, Dr. William M. M. Kirby, erroneously was permitted to testify that the reporting of data to the FDA by appellant did not measure up to the standards of the agency (Tr. 824, l. 9-839, l. 8). Nevertheless he admitted that an evaluation of drug application data requires exercise of scientific judgment. At page 839, line 24 we find the following:

> "(By Mr. Kelleher) In the evaluation of the information one that (*sic*, 'that one') requires, (speaking of the FDA), is the evaluation of the information submitted by the companies an evaluation that requires scientific judgment?
>
> "A. Yes.
>
> "Q. Are you familiar with that standard of scientific judgment required?
>
> "Mr. Bovingdon: No, wait a minute. There are as many scientific judgments as there are men scientifically qualified.
>
> "The Court: That objection is sustained." (Tr. 839-840)

Assuming that the jury found as a fact that there were either *fraudulent* or *negligent* deficiencies and inaccuracies in appellant's reporting of data to the FDA, should it have been permitted to draw the *inference* therefrom, that, if these deficiencies or inaccuracies had been known, the agency would have acted *differently,*

and then, upon the basis of that *inference,* further *infer* that the plaintiff (or through his conduit, Dr. Miller) would have acted *differently,* so that the damage would not have occurred? Is this not a somewhat classical example of basing inference on inference?

"Presumption may not be pyramided upon presumption, nor inference upon inference." *Neel v. Henne,* 30 Wn.2d 24, 37, 190 P.2d 775, 782; *State v. Willis,* 40 Wn. 2d 909, 914, 246 P.2d 827-830; *Johnson v. Western Express Co.,* 107 Wash. 339, 181 Pac. 693; *Mumma v. Brewster,* 174 Wash. 112, 24 P.2d 438; *Ruff v. Fruit Delivery Co.,* 22 Wn.2d 708, 720, 157 P.2d 730; *Prentice Packing & Storage Co. v. United Pacific Ins. Co.,* 5 Wn. 106 P.2d 314.

Mindful, however, of the rule probably established by this Court in *Allen v. Matson Navigation Co.* (CA 9th 1958) 255 F.2d 273,[16] that "the sufficiency of certain evidence to raise a question of fact for the jury . . . should not be controlled by state law,"[17] we respectfully invite the Court's attention to the following federal cases:

O'Brien v. Equitable Life Assurance Society of U.S. (1954, CA 8), 212 F.2d 383, cert. denied 348 U.S. 835 99 L.Ed. 658, 75 S.Ct. 57; *Tucker v. Traylor Engineering*

[16]Applying either California or Federal law the evidence would have been sufficient.

[17]As explained by Prof. James Wm. Moore. this view is in constitutional obedience to Article III and the Seventh Amendment and the Erie doctrine becomes subservient. 5 Moore Fed. Practice, 2dEd. Sec. 38.10 p. 102.

and Mfg. Co. (CA 10 Okla., 1931), 48 F.2d 783; *Looney v. Metropolitan R. Co.*, 200 U.S. 480, 488, 26 S.Ct. 303, 50 L.ed. 564; *Byrth v. United States* (1964 CA 8) 327 F.2d 917, cert. denied 377 U.S. 931, 12 L.ed.2d 295, 84 S.Ct. 1333.

Concededly, the oft-repeated statement that "inference may not be based on inference" has been questioned (Wigmore, Evidence 3rd Ed. Sec. 41), but while the clothes have been badly torn, the body remains intact.[18] Its mandatory *essence* persists. (See the 63-page annotation in 5 ALR 3rd 100.)

As stated in *Mitchell v. Machinery Center, Inc.* (1961 CA 10th), 297 F.2d 883, 885:

> "An inference is not a supposition or a conjecture, but is a logical deduction from facts *proved* and guesswork is not a substitute therefor." (Emphasis ours)

In *American Cyanamid Co., et al., v. F.T.C.*, 363 F.2d 757, 779 (CA 6, June 16, 1966), the Sixth Circuit Court vacated and remanded an order of the Federal Trade Commission, insofar as its decision held that the patent for tetracycline was issued as a result of improper conduct on the part of Chas. Pfizer & Co., Inc. and the American Cyanamid Co., on the grounds that there was not sufficient evidence. The Court, *inter alia*, said:

---

[18]In the (1966) ALR annotation, the annotator has stated that this "rule" has "shown amazing vitality." 5 ALR 3rd page 105.

> "The Commission's holding of improper conduct in the Patent Office proceedings is based on its findings that false and misleading statements were made to the Patent Office and that material information was withheld, resulting in the granting of the tetracycline patent to Pfizer."

Acknowledging that "the findings of fact of the Commission must be accepted by this Court if they are supported by substantial evidence on the record considered as a whole," citing 15 USC 45 (c), the Court later, making its point socratically, asks:

> "Would Lidoff's (the Patent Examiner) decision to grant the patent have been different if Cyanamid had revealed that it was in error in its prior assurances that there was no co-production of tetracycline in aureomycin? Or was he already aware of the facts which the Commission found to have been withheld by Cyanamid?
>
> "Finally, the ultimate questions are: Did Lidoff receive all the information he requested from Pfizer? And was Lidoff misled and deceived by Pfizer and Cyanamid and did he grant the tetracycline patent as the result of such deception?
>
> "It would seem that the answer by Examiner Lidoff to these questions might settle conclusively the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved.
>
> "Only Examiner Lidoff could have answered these questions. Yet the Commission failed to call him as a witness, although requested by petitioners to do so during the hearings. Instead the Commission introduced as a witness Mr. Manuel C. Rosa, Lidoff's superior in the Patent Office, who obviously could not answer questions concerning matters which were exclusively within the personal knowledge of Examiner Lidoff. Petitioners did not seek

> to subpoena Examiner Lidoff to testify as their witness, having been denied an opportunity to interview him in advance."

Then, after overcoming the Commission's argument that a Patent Office procedural regulation precluded use of the Examiner as a witness, the Court, returning to the "substantial evidence" question, states:

> "We find the decision of the Commission on this issue to be based on inferences and speculations and which are insufficient to constitute substantial evidence." Citing *Universal Camera Corp. v. N.L.R.B.*, 340 U.S. 474, 496; *N.L.R.B. v. Columbian Enameling & Stamping Co.*, 306 U.S 292, 300.

The instant appeal presents a striking parallel to the above-cited case. Dr. Talbot processed the appellant's new drug application and eventually made it effective by his letter dated April 19, 1960 (Ex. 95). He is the counterpart of Mr. Lidoff, the Patent Examiner, referred to in the language of the decision above-quoted. Paraphrasing the decision of the Sixth Circuit, would Dr. Talbot's decision to make the application become effective have been different if he had received all the information requested from Merrell or was he misled and deceived by Merrell and would not have granted the application as a result thereof? Only Dr. Talbot could have answered these questions. He did not appear as a witness.

The testimony of Dr. John O. Nestor, medical officer in the Food and Drug Administration, who assumed charge of MER 29 after it had been on the market a

year and three months, testified by deposition. He testified that he succeeded Dr. Talbot in October, 1961, after Talbot had left the administration (Tr. 712, 717, 727). He obviously would not have answered questions concerning matters which were exclusively within the personal knowledge of Dr. Talbot. Of course, Dr. Nestor was not permitted to so testify.

A fortiori, the instant evidence should be held insufficient to warrant the instructions given. The far greater remoteness from the *ultimate fact necessary to be established herein,* more than off-sets any arguable "quantum of proof" distinction based on the criminal nature of the cited case.

As pointed out in argument below, despite testimony during trial of Dr. John O. Nestor, *a medical officer in the Food and Drug Administration,* the Court was "treated to the interesting experience of having somebody else, in a *hypothetical* question, be asked to tell us what, in the circumstances, the FDA would have done or would not have done . . ." (Tr. 833, ll. 7-11). Of course, he was not permitted to so testify (Tr. 859, l. 19-860, l. 1). And even if it was proper (which we seriously question) for him to testify to his *opinion* that the quality of appellant's reporting was below the FDA standard, still such testimony is clearly ineffectual to close the gap of which complaint is herein made.

Moreover, we respectfully invite this Court's attention (at least in respect to the "fraud" instruction) to

defendant's Exhibit A-13 (Tr. 1372), the agency's order of May 22, 1962, formally suspending the New Drug Application (usually referred to in the record as the NDA) after the company's earlier withdrawal of MER 29 from the market on April 17, 1962 (Tr. 1646, ll. 17-19). This order states the findings upon which it is based as required by 21 USC 355 (e).[21] It will be noted that the suspension was under the language of subsection (1), "that clinical experience shows that MER/29 (triparanol) capsules are unsafe for use under the conditions of use upon the basis of which said application became effective." *The order was not based on subsection (2),* "that the application *contains any untrue statement of a material fact.*"

The last sentence of section (e) of 21 USC 355, *i.e.* that "(T)he order shall state the findings upon which it is based," would appear mandatory. Is there not a presumption that an agency of the Government complied with the law?

> "As to the first factor (where individual rights are concerned), almost without exception, courts have held that the determination of an administrative agency as to the existence of a fact or status which is based upon a present or past group of

[21] (e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

> facts which may not thereafter be altered or modified." *Olive Proration Program, etc. v. Agricultural P. Commission,* 17 Cal.2d 204, 109 P.2d 918 (1941).

True, the statement last quoted may be directed to the finality of administrative actions as respects the citizen and the agency. Yet, when there is ever present such a strong presumption that public officers have performed their duty (see scores of cases digested in 21 Modern Federal Practice Digest, Evidence, Sec. 83 (1)), does not a third party, a stranger to the agency action, bear a heavy oar? Particularly, should not this be so when the duty-prescribed act of the agency required to be refuted is, in effect, its very act of exculpating from fraud the party with whom it dealt?

Interestingly, appellee took exception to the same instruction on fraud as is the basis of appellant's complaint in Specification IV. Apparently fearful of appellate scrutiny, appellee raised the point that the instruction *was proposed by appellant* — perhaps hoping to immunize his case from error by resort to the well-established rule that a party waives his right to object to instructions which he has proposed.

We might prophylactically answer this anticipated position by pointing out that appellee, throughout the trial, made it abundantly clear to the trial judge that the jury should be permitted to find that a proximate cause of appellee's injuries was the alleged fraud perpetrated on the FDA or the alleged negligent reporting of data.

Of the disputed facts alleged by plaintiff, as summarized by the Court we find:

> "9. That the defendant falsified and omitted data known to it in its New Drug Application. That some of such falsification and omission may have been willful; some of it may have been negligent.
>
> * * *
>
> "13. That the above-mentioned falsifications, omissions, concealments and statements were made with the intent of causing the New Drug Application named as NDA to become effective so that defendant could market MER 29. And that *as a result thereof, the NDA became effective* and defendant was allowed to market MER/29." (Tr. 1649-1650) (Emphasis ours)

In stating the issues for the jury's determination, the Court charged:

> "Another Issue of Fact for the jury's determination: Was there any fraud, deceit or concealment practiced by the defendant?
>
> "Another such issue for your determination is: If there was any fraud, deceit or concealment practiced by the defendant, did it result in any damage to the plaintiff?"

In answering a leading question (not objected to) Dr. Miller, appellee's treating physician, testified to his reliance on FDA approval.

> "Q. (By Mr. Kelleher) When you prescribed this drug for Mr. Golden, upon what did you rely? Will you give us what, or several things upon which you relied for that information and knowledge on your part as to the efficacy of the safety of the drug?
>
> "A. First of all, the drug needs to be approved by the Federal Drug—Food and Drug Administration, and I feel if it has been approved by them it

is a safe drug . . ." (Tr. 135, l. 22-136, l. 5)

No doubt to energize the causal conduit, and despite some strain on one's credulity,[22] we find appellee (the patient) testifying:

> "Q. In taking this drug, what did you rely on?
> "A. I relied on Dr. Miller and the government.
> "Q. How do you mean the government?
> "A. Dr. Miller indicated to me that this drug had been approved.
> "Q. By whom, did he say?
> "A. It had been approved by the Federal Drug Administration." (Tr. 627, ll. 9-16)

In responding to argument in support of a directed verdict on the issue of fraud, appellee's counsel was invited by the Court to

> ". . . point out compliance with each one of the requirements[23] as set out in Williams v. Joslin in the State Court, under the state rules, that is in 65 Washington 2nd begining 696 —" (Tr. 1015, ll. 19-23)

In answering the Court's request, counsel went through the first eight of the nine requirements—with the *FDA* for the most part *in the role of the person defrauded* (Tr. 1016-1020). Then as to the *ninth* requirement, as if by some legal legerdemain, he deftly closed the causal chasm by the following statement:

> "I think the law is quite clear that Mr. Golden is

[22]Earlier on deposition appellee testified as appears at (Tr. 628, ll. 1-7). The discrepancy was not explained but we realize the jury was not bound to consider this circumstance.

[23]These are the 9 requirements set forth in the court's instructions set forth under Specification II, *ante*.

> entitled to rely upon the Food and Drug Administration as a citizen to protect him on questions of toxicity at that time from drugs and he did so rely." (Tr. 1020, ll. 22-25)

We respectfully suggest that what appears to be appellee's present predicament simply stems from "overselling" a conscientious trial judge on this theory of causal relationship. The job of "selling" apparently was so well done that, despite both parties excepting to the same instruction, at a time when the jury had not yet retired, this instruction was not withdrawn. The exception made by appellee has the flavor of a tardy, post-action, "I didn't really mean it" response, *i.e.* the instruction

> "injected into the case an element which, *while plaintiff's counsel believes is the law,* is nevertheless *not already established* law . . ."

When one party, throughout a trial, insists on a certain legal position, succeeds in convincing the Court to adopt that position as correct, and the Court makes clear that there will be an instruction given thereon, has the opponent, who vigorously, but unsuccessfully, resisted the adoption of such position by the Court, waived his right to object to such instruction because it was submitted by him? Unless substance be completely subordinated to form this question must be answered, "No." And the cases so hold:

Sorensen v. Western Hotel, Inc. (1960) 55 Wn.2d 625, 349 P.2d 232; *Folden v. Robinson* (1961) 58 Wn.2d

760, 364 P.2d 924; *North Chic. Elec. Co. v. Peuser* (1901) 190 Ill. 67, 73, 60 N.E. 78.

The first cited case is not too unlike the case at bar. On page 637 (349 P.2d 240), the Washington Court says:

> "The plaintiff vigorously and plausibly argues that having requested and failed to except to an instruction which says, 'You are instructed that the ramp was maintained in violation of the Ordinances passed by the City of Bellingham,' that instruction became the law of the case, see *Schneider v. Noel* (1945), 23 Wn.2d 388, 160 P.2d 1002.
>
> "(6) We have held that an adequate exception to one of two or more instructions subject to the same error is sufficient to challenge the consideration of the trial court, which is the purpose of the exception, and to bring the question here for review. *Crutcher v. Scott Publishing Co.* (1953), 42 Wn.(2d) 89, 104, 253 P.(2d) 925; *Franks v. Department of Labor & Industries* (1950), 35 Wn.2d 763, 770, 215 P.(2d) 416. *The added element in this case is that appellant proposed the quoted instruction.*
>
> "(7) The purpose of the rule requiring exceptions to the instructions is to advise the court of the error claimed. If there was anything in this trial, as to which the plaintiff and the trial court were well advised, it was that the defendant hotel was contending that the 1953 ordinance adopting the uniform building code was not retroactive in its application, and that it was not applicable to the ramp on which the plaintiff slipped and fell. The trial court had ruled that the ordinance was applicable; had admitted it in evidence over strenuous objection; had indicated his intention to give instructions Nos. 6 and 7, to which we have referred, despite the plaintiff's exceptions thereto. It is clear that instruction No. 8 was a proximate-cause instruction, and the defendant had nothing left to

argue about, except proximate cause. Instructions Nos. 6 and 7 amounted to a directed verdict, if the grade of the ramp and the absence of hand rails was a proximate cause of the plaintiff's slip and fall. Under these circumstances, the defendant hotel waived nothing by requesting instruction No. 8. As the supreme court of Illinois said in *North Chicago Electric Ry. Co. v. Peuser* (1901), 190 Ill. 67, 73, 60 N.E. 78,

"' . . . Being unable to induce the court to instruct the jury according to its view of the true legal principle affecting its right; the appellant company then presented a series of instructions embodying the theory of the law on the point as held by the court, as the most favorable declaration from the court to the jury possible to be obtained. The appellant company was not required to abandon all chances of a favorable verdict because the court would not grant an instruction to which it believed it was entitled. Without impropriety or the loss of the right to complain of the refusal of the court to declare the law as the company believed it to be, counsel for the appellant company might prepare instructions applicable to its cause in that view of the law which the court had announced that it entertained.

" 'The appellant company was powerless to combat the view of the court otherwise than by excepting thereto and preserving such exceptions, as was here done. The position in the trial court and in this court are in nowise inconsistent. It urged there the same theory of the law that it urges here, and it is nowise at fault for the error which occurred, and consequently not estopped.'

"See also *Wallner v. Chicago Consolidated Traction Co.* (1910), 245 Ill. 148, 153, 91 N.E. 1053.

"The defendant hotel only asked for an instruction as to proximate cause embodying the trial court's theory of the law which had been chosen over the objection of the defendant. The appellant neither mislead nor invited the court into error; there was no waiver and no estoppel." (Italics ours)

Also, see 89 C.J.S., Trial, Sec. 668, and *Williams v. Powers* (CCA Ohio, 1943) 135 F.2d 153.

It will be noticed that the *Sorenson* case considers as sufficient an objection to one of two instructions, both of which concern a common objectionable feature. This makes sense if the purpose of objecting to instructions is truly and genuinely to apprise the trial judge of error claimed.

And, of course, there could be no question of proper apprisal here considering appellant's arguments on its motions under FRCP 50a (Tr. 993 *et seq.*, 1532 *et seq.*).[24]

Another way of analyzing the question of legal sufficiency of the evidence to establish causation is to go directly to the substantive law governing proximate cause. When this is done, again it remains clear that the required legal proximity of relationship did not exist. One may simply ask the hornbook type question, "Was the alleged negligent act of reporting incomplete or inaccurate data to the FDA a necessary and indispensable antecedent to the harm that resulted?" The answer, obviously, is "No."

The Supreme Court of the State of Washington has *expressly* refused to substitute the "materially contrib-

[24]Query? When there is no "matter to which he objects" in an instruction, but complaint is simply that the issue covered should not be submitted and his position has been made clear, does Rule 51 even apply? See, application of the Washington Court Rule RPPP 51.16W in *Greenwood v. The Olympic, Inc.*, 51 Wn.2d 18, 315 P.2d 295.

uted" or "substantial factor" test either as a definition of or as a substitute for "proximate cause." *Blasick v. Yakima*, 45 Wn.2d 309, 274 P.2d 122. And see *Gardner v. August Seymour*, 27 Wn.2d 802, 180 P.2d 564; *Mathers v. Stephens*, 22 Wn.2d 344, 156 P.2d 227; *Everest v. Rilkan*, 26 Wn.2d 542, 174 P.2d 762.

ARGUMENT RE SPECIFICATIONS III and IV

These specifications, which are based on claimed error in denying defendant's motions for a directed verdict on the issue of fraud, particularly as related to fraud on the FDA, we feel are amply covered by the preceding argument respecting specifications I and II. We might add only, that in arguing these motions, appellant made known to the Court his objection to the Court's theory of causal relationship which of course would apply whether the act of misreporting data to the FDA were either fraudulent or *negligent*. Specifically, we call this Court's attention to page 1000 of the transcript, l. 19 through page 1002, l. 18 and page 1003, l. 21 through page 1004, l. 4. Also page 1534, ll. 6-10, ll. 18-23, and page 1535, ll. 14 through 18.

ARGUMENT ON SPECIFICATIONS V, VI, VII and VIII

A. First, Did the Evidence, Viewed in a Light Most Favorable to Plaintiff, Warrant the Submission of the Issue of *Express* Warranty?

Appellee testified:

"Q. . . . How did you accomplish the refilling of the prescriptions?

"A. The doctor would call the druggist and direct him to refill the prescription.

"Q. And you in turn would call the doctor by phone and say you were out?

"A. That is correct." (Tr. 622-623)

"Q. Is it true, sir, then that you never saw the folded piece of paper which you now hold in your hand which was A-1 for identification or the box in which it was contained?

"A. I never saw the folded piece of paper or the box which it was contained in, prior to seeing it in this court room." (Tr. 614)

In respect to Exhibit 13:

"Q. So each and every time you got a bottle of those it would be in the same form as that?

"A. That is correct." (Tr. 13)

As will be seen, Exhibit 13, the "re-package," was as described by Dr. Miller on pages 145 and 146. The original package (Ex. A-1) insert

"tells the composition of the drug, the advantages of the drug, how the drug acts, the clinical results, discussion of the drug, side effects, the pharmacology of the drug, the indications for the drug, the cautions, and the use of the drug, the dosage and administration and package information and references." (Dr. Miller, Tr. 146-147)

This brochure

"is ordinarily not given (to the patient) unless the doctor orders that it be given."

He did not order it given to Mr. Golden (Tr. 147-148). Ex. A-1 was the form in which appellant's product was sold to pharmacies (Tr. 1229).

From the foregoing testimony it clearly appears (and a search of the entire record confirms) that at no

time were any express warranties made to appellee by appellant, certainly no privity existed between them and, moreover, the packaged product sold by appellant to the North City Pharmacy was not even the same package that North City Pharmacy sold to appellee.

The law of the State of Washington, although threatened[25] with some future "once and for all" destruction by the court itself, *continues* to be that, if there is no contractual privity attending a sale, there can be no warranty, express or implied. The exceptions that have been engrafted since *Mazetti v. Armour,* 75 Wash. 622, 135 Pac. 633, in 1913, and especially since *Baxter v. Ford Motor Co.,* 168 Wash. 456, 12 P.2d 409, in 1932, concededly have been numerous and they are said to fall into three categories: (1) where the article causing the injury is of a noxious or dangerous nature, (2) where fraud or deceit has been shown on the part of the offending party, (3) where the manufacturer has been negligent in some respect with reference to the sale or construction of an item not imminently dangerous. *Cochran v. McDonald,* 23 Wn.2d 348, 161 P.2d 305 (1945); *Dobbin v. Pac. Coast Coal Co.,* 25 Wn.2d 190, 170 P.2d 642 (1946); *Kramer v. Carbolineum Wood Preserving Co.,* 105 Wash. 401, 177 Pac. 771 (1919); *Kasey v. Suburban Gas Heat,* 60 Wn.2d 468; *Dimott v. Ernie Major, Inc.,* 55 Wn.2d 385, 347 P.2d 1056.

Such cases that may appear to the contrary have re-

[25] *Freeman v. Navarre,* 47 Wn.2d 760, 289 P.2d 1015.

sorted usually to the fiction of agency. See, *Freeman v. Navarre,* 47 Wn.2d 760, 289 P.2d 1015 (1955), and *Wisdom v. Morris Hardware Co.,* 151 Wash. 86, 274 Pac. 1050 (1928). Obviously, the pattern of "agency" to which resort was made in those cases does not fit the quadric relationship between plaintiff, defendant, pharmacy, and doctor herein.

Of course, the presently existing state law governs. 28 USC 1652; *Erie R. Co. v. Tompkins* (1938) 304 U.S. 64, 58 S.Ct. 816, 82 L.ed. 1188. And, it is respectfully suggested that, although this Court must use "its best judgment" of what the Washington Court would hold, absent any pronouncement on the law (*Tavernier v. Weyerhaeuser Co.,* 309 F.2d 87), still, this rule should not obtain where the law has been pronounced, albeit criticized, but not yet overruled.

B. Evidence of the *Composite* Representation *Legally Negates* Express or Implied Warranty

Apart from a clear lack of privity, is the *complete* picture (using only *appellee's* evidence, together with *admitted* and *uncontroverted* facts) of the representations, including conditions, qualifications, and recommendations for use of the product, such as to *legally* support either an express or implied warranty in this case where the subject matter of the representations is a *prescription new drug?*

Assuming arguendo, that established reliance by the doctor is reliance by the patient, let us first examine the

admitted representations *in toto*. Dr. Miller's own testimony reveals:

As to his first meeting with a detail man (drug salesman) on February 17, 1960,

> "A. I am not too clear as to what was said at the various times that I saw the detail man from Merrell, but I do recall that, and I believe that this was on February 17, 1960, that the detail man informed me about this drug that was going to be introduced to the medical world that would be used to lower the blood cholesterol and I believe that this was on February the 17th, 1960, but I am not certain of this." (Tr. 68, l. 25-69, l. 8)

On July 12, 1960,

> "A. Yes, I do remember about that. Two of the detail men from Merrell came in this day and they gave me a brochure explaining about MER/29, and we discussed this medication and its role in lowering of the cholesterol metabolism and the lowering of cholesterol, and they spoke very favorably of the medication and certainly then sounded like a very important thing." (Tr. 69, ll. 15-22)

On that occasion the doctor was delivered Exhibit 2 (Tr. 70). Animal tests were not discussed on either of these occasions (Tr. 74).

At one of those earlier meetings apparently,

> "A. They told me that as far as their knowledge was concerned, and the company knowledge, that this drug was very free of toxic or side effects and in that it could be used safely." (Tr. 74, ll. 20-23)

The doctor next saw the detail man on September 12, 1961 and described this meeting as follows:

> "A. I think that this was just a routine call and

> I don't remember what was discussed except that I am, I don't recall of any mention of any side effects from MER/29, and I know every time—I am generalizing now, but every time I did see the Merrell man we did discuss the effects on the cholesterol and agreed that it was effective in lowering cholesterol to a certain degree, and I know also in a general way that I always asked the detail man about possible side effects." (Tr. 82, ll. 2-11)

Between September 12, 1961 and the next call of the detail man on October 17, 1961, one of the doctor's patients brought him a McCall's magazine article (Ex. 5) which mentioned hair and skin changes in connection with MER/29 therapy (Tr. 82-86). At the October 17, 1961 meeting he discussed the article with the detail man, believed to be Mr. Moberg, and

> "He told me *to his knowledge* there were no serious side effects to this medication, and that I could prescribe it with a feeling of safety." (Tr. 86, ll. 12-15)

At the final meeting testified to, December 12, 1961,

> "A. I think our conversation had been very similar as to what it had been in the past: MER/29 was a safe medication to take, and that it was effective." (Tr. 87, ll. 16-18)

During this period Dr. Miller remembered receiving literature from the Merrell Company concerning MER/29.

> "Q. (By Mr. Kelleher) Had you up to this time ever gotten any communication or literature by mail or telegraph or otherwise directly from the company, the Merrell Company, concerning MER/29?
>
> "A. Yes, I had.

"Q. And what can you tell us about it to the best of your recollection?

"A. I don't recall exactly when I received this information, but it was very encouraging, the reports of the use of this MER/29.

"Q. What form was the communication?

"A. I don't recall for sure." (Tr. 86, l. 19-87, l. 5)

Throughout the parade of medical witnesses there was unanimity of opinion on the proposition that no drug was "safe." Dr. Miller acknowledged that "all drugs have potential side effects . . . " (Tr. 160, l. 1) and felt that " . . . any side effect is potentially serious . . . " (Tr. 142, l. 7).

In February of 1960 he had read the following written representation: "It is concluded that MER/29 is an effective drug for lowering serum of cholesterol and *warrants further investigation*" (Tr. 168, ll. 8-11) (emphasis ours).

In July, 1960, more than two months prior to prescribing the new drug for appellee, he read an article given to him by the detail man of appellant which stated, among other things, that, "longer observations in a larger group of patients (nine patients) with more detailed toxicity tests are necessary *to establish fully the use and safety of* MER 29 in coronary artery disease" (Tr. 170, l. 21-171, l. 1) (emphasis ours).

He read information in writing by the company, before he prescribed the drug which stated,

> "The specific site of action of MER/29 is now known to be between desmosterol reported to be the last precursor in the synthesis pattern and cholesterol. Although greater than normal quantities of desmosterol can be qualitatively shown in the liver and blood of animals and the blood of human beings treated with MER/29; reduction of total steroid suggests little accumulation. The significance of the presence of this substance is *unknown* and *speculative.*" (Tr. 182, ll. 20-25, Tr. 183, ll. 1-7) (emphasis ours)

He used his Physicians' Desk Reference several times a day (Tr. 141, l. 2) and, in respect to MER/29, it contained the admonitory words that " . . . *lifetime effects are unknown. Periodic examination of patients on prolonged MER/29 is therefore recommended*" (Tr. 81, ll. 18-21).

Dr. Miller had known appellee a long time (Tr. 107, l. 24), it was important that he know his patient's psychological makeup (Tr. 108, l. 11), he had spent considerable time with him on annual physical examinations in the past (Tr. 109, ll. 8-9), and he knew appellee was a patient who de-emphasized symptoms (Tr. 127, ll. 7-9), and felt that, as a patient, "he really (didn't) complain enough" (Tr. 127, l. 4).

Again,

> "I think that he would have a tendency to not call the physician as early as he otherwise might, and perhaps to even ignore certain symptoms and not discuss them at all unless the doctor, unless I ask him specifically about them." (Tr. 128, ll. 8-22)

The doctor saw appellee two times in 18 months (Tr. 161)!

Even though we must accord to a prevailing party's testimony all favorable inferences, it would seem that where there are *admitted* facts which dictate a necessary *legal* result, that these *admitted* facts may not be swept under the rug.

Peculiarly, within the field of prescription new drugs, where, as here, the alleged representation is a *composite* of oral and written statements, should the trier of fact be permitted to *edit* those statements? Instead, must not the Court in the first instance, on the basis of the entire composite representation, including any conditions, qualifications and recommendations for use, determine whether the evidence at best would *legally* support a finding of either express or implied warranty?

(It might be noted here that the Court below, with all due respect, seemed disinclined to decide *specifically the applicable law*, but instead furnished the jury with an abundance of abstract law and appeared to ask it to determine which parts of that law fit the facts as they found them — whereas usually the specific applicable law is first determined by the Court and the jury simply determines whether the facts by them found fit the law (Tr. 1662, ll. 7-11, 1664, ll. 21-25, 1538, ll. 7-10)).[26]

[26] In *Lynch v. Oregon Lumber Co.* (CA 9th, 1939) 108 F.2d 283, at 287, this court said "this instruction clearly illustrates a lack of separation between law and facts." And see *Decker v. Korth*, 219 F.2d 732.

We earnestly submit that the "composite" representations, allegedly relied upon under Dr. Miller's own testimony, admitted and uncontroverted facts, clearly shows this to be a conditional and qualified representation which as a matter of law prevented the issues of either express or implied warranty from properly being submitted to the jury.

C. Should the Usual Implied Warranty of Fitness for Use Be Applied to Prescription Drugs?

A prescription drug case is quite *sui generis*—far different from the case where a manufacturer concocts an ineffective conglomeration of herbs and passes the product off as an arthritic cure (*Research Laboratories v. U. S.,* 167 F.2d 410 (CA 9 Wash.)), or where a poison is not labeled (*Forney v. Sears,* 153 Wash. 615, 280 Pac. 56), or where use of a cosmetic or drug sold to the general public results in harm (*Esborg v. Bailey Drug Co.,* 61 Wn.2d 347, 378 P.2d 298). Here, the fact that a doctor is prescribing makes a difference. *Marcus v. Specific Pharmaceuticals, Inc.* (1958) 191 Misc. 285, 77 N.Y.S.2d 508, and *Wechsler v. Hoffman-LaRoche, Inc.* (1950) 99 N.Y.S.2d 588. See *Magee v. Wyeth Laboratories, Inc.,* 29 Cal. Rptr. 322 (Cal. App. 1963), and *Love v. Wolf,* 38 Cal. Rptr. 183 (1964).

See comment K to Sec. 402 A, Restatement of Torts (2d). (Also 79 A.L.R.2d 377, *et seq.;* 33 Tenn.L.Rev. 323).

The law of Washington is not established in respect to *prescription* drugs. Prophetic interpretation may be necessary. *Cooper v. American Airlines* (CA 2d, 1945) 149 F.2d 355; *Tavernier v. Weyerhaeuser Co.*, 309 F. 2d 87.

"As long as there is diversity jurisdiction, 'estimates' are necessarily all that federal courts can make in ascertaining what the state court would rule to be the law." Mr. Justice Frankfurter concurring in *Bernhardt v. Polygraphic Co.* (1956) 350 U.S. at 209, 76 S.Ct. at 279, 100 L.ed. at 208.

What are the clues?

In *Gile v. Kennewick Public Hospital,* 48 Wn.2d 774, 296 P.2d 662 (1956) the Washington Court held that a breach of warranty cause of action, in respect to an alleged "sale" of blood to a patient by a hospital, was properly dismissed because, although a specific amount of money was charged the patient, this was an item furnished incidental to the contract of service between the hospital and patient.

Esbory v. Bailey Drug Co., 61 Wn.2d 347, 378 P.2d 298, may be helpful although the product was non-prescription.

Too, it is not likely the Washington Court, which pioneered the doctrine of implied warranty of fitness in food cases, will overlook the fact that the *public health* was the compelling inducement. *Cochran v. McDonald*, 23 Wn.2d 348, 161 P.2d 305 (1945) at p. 354. It is not to

be expected that the Court would overlook the contribution to the public welfare that has been made by the producers of prescription drugs. We respectfully suggest that, when a case involving prescription drugs arises, the Washington Court might well be reluctant to extend implied warranty to this narrow field.

Often Federal Courts, in the absence of more to go on resort to the Restatement of the Law (e.g., *Hodges v. Johnson* (W.D. Va. 1943) 52 F.Supp. 488). See Restatement of Torts (2d) Sec. 402 A (j and k).

In this case the Restatement is not applicable. § 402A provides, among other things:

> "(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> "(a) The seller is engaged in the business of selling such a product, and
>
> "(b) It is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."

The product, the prescription drug, MER/29, did not reach Mr. Golden, the plaintiff, without substantial change in the condition in which it was sold by the manufacturer, Richardson-Merrell, Inc. The druggist repackaged it, discarding the package insert that had the approval of the Food and Drug Administration. Furthermore, the appellee failed to prove that the drug was defective in any way. Appellant proved the contrary (Tr. 1107-1115)

ARGUMENT ON SPECIFICATION IX

Exhibits 97-104, 108 deal with promotional material of the appellant. Strenuous objection was made to the introduction of these exhibits on the ground that both the prescribing doctor and the detail man had testified and yet these exhibits were not linked up with any conversation that the detail man had with the doctor. There is no evidence whatsoever that the prescribing doctor relied on any of them (Tr. 68-87). The principal elements of express warranty are an affirmation of a fact or promise by the seller and reliance thereon by the buyer. *McDonald Credit Service, Inc., v. Church* (1956) 49 Wn.(2d) 400; 301 P.(2d) 1082; *Jeffery v. Hanson* (1952) 39 Wn.(2d) 855; 239 P.(2d) 346; *Eliason v. Wilker* (1953) 42 Wn.(2d) 473; 256 P.(2d) 298. The introduction of these exhibits only served to confuse the jury with respect to the issue of warranty.

CONCLUSION

It will be noted that appellant has foregone assigning error to excessiveness of the $150,000.00 verdict. The reasons are two-fold. Being as objective as we can, we suspect that this Court might well feel that we are arguing about excessiveness from appellant's standpoint only—not from appellee's, but more importantly, we have foregone said assignment lest it detract in any way from the sincerity of our insistence that plain error herein exists.

Although not claiming error on excessiveness, but, be-

cause an error that may not be prejudicial against the backdrop of one trial may be prejudicial in another, we feel it not amiss to invite the Court's observation of the necessarily present, but nonetheless, repulsion-inciting atmosphere of such a trial with the claimant's understandable emphasis on laboratory animal testing — where the appellant's technicians were deliberately killing animals, some of whom were dogs, in order to determine lethal dosage, and then were cutting them up to inspect the parts. The refinement of language to "termination," dissection" and "autopsy" can hardly be expected to overcome the layman's inherent empathic proclivities when simple ear-pulling of twin beagles has been known to rattle the public's political pulse.

In applying the law to the issues of which review is respectfully asked, we urge a studied notice of the *fundamental* distinction between the sale of a *prescription* drug and other food and drug articles intended for human consumption. In the ordinary sense a consumer cannot buy a prescription drug. True, these are available to men who are highly trained in the health sciences to use, subject to the exercise of their individual judgments, as an adjunct in the treatment of various ailments. In exercising that judgment the doctor knows that he is not making use of a substance that is *safe*.

[27]Indeed, the description provided by statute is a drug "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; . . ."

He knows that *every ethical drug has potential side effects;* that if it did not affect the bodily processes it would be an innocuous and worthless placebo. The very purpose of making their sale generally illegal is because such drugs are not safe.[27] When the patient goes to the pharmacy with a "written order of his doctor" which in effect says, "Please furnish to my patient 30 capsules of MER/29—give him written instructions to take them in this manner—he will pay for them," certainly it is nothing that the patient says that makes a contract of sale. In effect, this is part of the *physician's treatment* of the patient.

When this is understood, it is not at all strange to find proverbially "litigation-reluctant" doctors chameleonically becoming almost advocates of their patient's cause in this type of case.

Courts, of course, are quite aware that the liberalization of the law in the field of products liability was to better the balance between consumer and manufacturer. But the ever-steadying hand of the judiciary well knows that one does not right a listing boat by overloading the other side. The *carte blanche* enjoyed by appellee below did not accord with justice.

Courts well know the ease with which one may point a finger and shout, "You should have known!" But does not pointing it so quickly appear unbecomingly captious of those members of a profession which has so recently borne the cross of having blinded so many

thousands of our country's pre-mature babies? And this done quite *innocently,* under *approved* therapy, where the *"toxic"* substance was *just plain oxygen.*[28]

The query is posed: Is it fair that the full responsibility be borne by the manufacturer for the harm that results from a "medically sought after" bio-chemical process within the human body? In the instant case no one has ever contended that there was a single thing unwholesome or adulterated about MER/29—indeed, this "was just what the doctor ordered." Appellant responded to a demand for an unadulterated drug that would lower cholesterol. Richardson-Merrell developed just that—it worked. Unfortunately, the artificial reduction of cholesterol in certain patients is harmful.

The foregoing considerations have been made, and this Court's attention invited to them at the risk of being accused of "jury argument," only because we earnestly feel that "products liability" law as applied to *prescription* drugs still sails an uncharted sea—and certainly some policy observations are proper.

It is a matter of common knowledge that the amendment of mortality tables upward, the conquering of formerly fatal diseases, the enjoyment of vastly better health by the general public has in no small part been by the contributions to medicine of new drugs—by just

[28]This reference to "retro-lental fibroplasia" is *dehors* the record, but was a matter of public news; *e.g.* See *N.Y. Times*, May 2, 1954, Sec. IV, p. 9, col. 5; Sept. 23, 1954, page 41, col. 7; Sept. 26, 1954, Sec. IV, p. 9, col. 6.

such manufacturers as appellant. Dread diseases yet hold out their dare. They will be conquered. Health is perhaps the most fundamental ingredient in public welfare. Efforts that have been so magnificently ameliorative in the past should not be unnecessarily hampered in the future—nor should the average citizen be penalized by increased drug prices because of an unwarranted liberalization of the law respecting this type of manufacture. We must guard against "cutting off our nose to spite our face." We suggest that the syllogistic argument that, because the law has properly seen fit to clear of legal obstacles the path to the door of those who manufacture articles for personal human consumption —and, because a prescription drug is an article for human consumption, an equally clear path should be opened—bears the closest scrutiny.

The *purpose and origin* of legal principles should be ever borne in mind.

We are reminded of what the Washington State Supreme Court, a pioneer in the extension of manufacturer's liability, said in *Cochran v. McDonald,* 23 Wn. 2d 348, 161 P.2d 305 (1945) at p. 354:

> "When our food cases are critically examined, it will be found that the rules pronounced in them are exceptions to the general rule of the law of sales. The position taken was justified on the ground that, when such an article as food for human consumption is considered, a question of *health* is involved, and *public policy and the ends of social justice demand a rule be applied that will aid in the protection of health.*"

Can the public health best be aided (where prescription drugs are involved) by anything less than a *strict* and *careful* application of the law of proximate cause, of fraud and of warranty? We most earnestly urge such application. In so doing we are, of course, respectfully asking only for justice.

Respectfully submitted,

GEORGE H. BOVINGDON
Attorney for Appellant.

ORVIN H. MESSEGEE.
Of Counsel.

CERTIFICATE OF SERVICE

I certify that, in connection with the preparation of this brief, I have examined Rules 18 and 19 of the United States Court of Appeals for the Ninth Circuit, and that, in my opniion, the foregoing brief is in full compliance with those rules.

GEORGE H. BOVINGDON

SHERWOOD E. SILLIMAN
Attorney for Appellant.

Appendices

APPENDIX A

§ 355. New drugs—Necessity of effective application

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

Filing application; contents

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Effective date of application

(c) An application provided for in subsection (b) of this section shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing

thereof) as the Secretary deems necessary to enable him to study and investigate the application.

Grounds for refusing application to become effective

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

Suspension of effectiveness of application

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for

hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

Revocation of order refusing effectiveness

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

Service of orders

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

Appeal from order

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his

principal place of business, or in the United States District Court for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence.

shall be conclusive, and his recommendations, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 225, 346, and 347 of Title 28, as amended, and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia," approved February 9, 1893. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

Exemption of drugs for research

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs. June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub. L. 86-507, § 1(18), 74 Stat. 201.

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WITNESSES

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WITNESSES—Continued

APPENDIX B

EXHIBITS

Plaintiff's

Exhibit Number	*Marked*	*Admitted*
1	58	58
2, 2a, 2b, 2c	71	71
3	77	79
4	78	79
5	84	84
6	92	93
7	97	102
8	98	102
9	113	114
10	113	116
11	114	117
12	120	121
13	132	148
14	149	150
15	149	150
16	200	202
17	210	211
18	237	355
19	247	975
20	259	261
21	272	273
22	272	276
23	297	299
24	320	321
25	330	330

Plaintiff's—Continued

Exhibit Number	*Marked*	*Admitted*
26	347	Rejected
27	367	368
28	367	368
29	369	371
30	369	371
31	370	371
32	370	371
33	370	371
34	370	371
35	370	371
36	381	381
37	388	388
38	392	Rejected
39	399	399
40	401	402
41	418	420
42	432	432
43	433	433
44	433	434
45	434	434
46	434	896
47	434	435
48	434	436
49	434	897
50	434	902
50a	434	898
51	434	585

Plaintiff's—Continued

Exhibit Number	*Marked*	*Admitted*
52	434	903
53	434	585
54	434	906
55	434	586
56	434	Rejected
57	434	911
58	434	911
59	536	544
60	551	551
61	552	552
62	556	558
63	556	558
64	558	560
65	578	579
66	653	654
67	654	976
68	664	666
69	664	666
70	721	722
71	726	726
72	729	Rejected
73	775	779
74	779	793
75	779	794
76	787	788
77	787	788
78	787	788

Plaintiff's—Continued

Exhibit Number	*Marked*	*Admitted*
79	787	788
80	787	980
81	787	
82	787	982
83	787	982
84	787	Rejected
85	787	"
86	787	"
87	787	"
88	787	787
89	787	Rejected
90	787	"
91	787	788
92	787	788
93	787	788
94	787	788
95	800	800
96	Withdrawn	
97	933	936
98	940	951
99	940	951
100	945	946
101	952	953
102	953	956
103	957	958
104	959	960
105	961	961
106	962	963

Plaintiff's—Continued

Exhibit Number	*Marked*	*Admitted*
107	965	965
108	967	968
109	1152	1159
110	1203	1212
111	1264	
112	1319	
113	1522	1541
114	1525	1541
115	1529	1541
116	1530	1541

EXHIBITS

Defendant's

Exhibit Number	*Marked*	*Admitted*
A-1	143	1229
A-2	Withdrawn	
A-3	1043	Rejected
A-4	1050	1191
A-5	1050	1191
A-6	1052	1053
A-7	1054	1054
A-8	1080	1091
A-9	1085	1092
A-10	1085	1092
A-11	1121	1448
A-12	1285	1314
A-13	1372	1373
A-14	1387	1387